

PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Possession, Use, and Transfer of Select Agents and Toxins 42 CFR 73

Possession, Use, and Transfer of Select
Agents and Toxins; Public Meeting
December 16, 2002

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Signed: June 12, 2002

- **Possession / Registration**
 - National Database
- **Security Risk Assessment by DOJ**
 - Entity and individual
 - Restricted Persons (USA Patriot Act)
- **Exemptions**
- **Nondisclosure of information**
- **Criminal penalties**
- **Notice of Possession**
- **Coordination with USDA**

STATUTORY TIMELINE

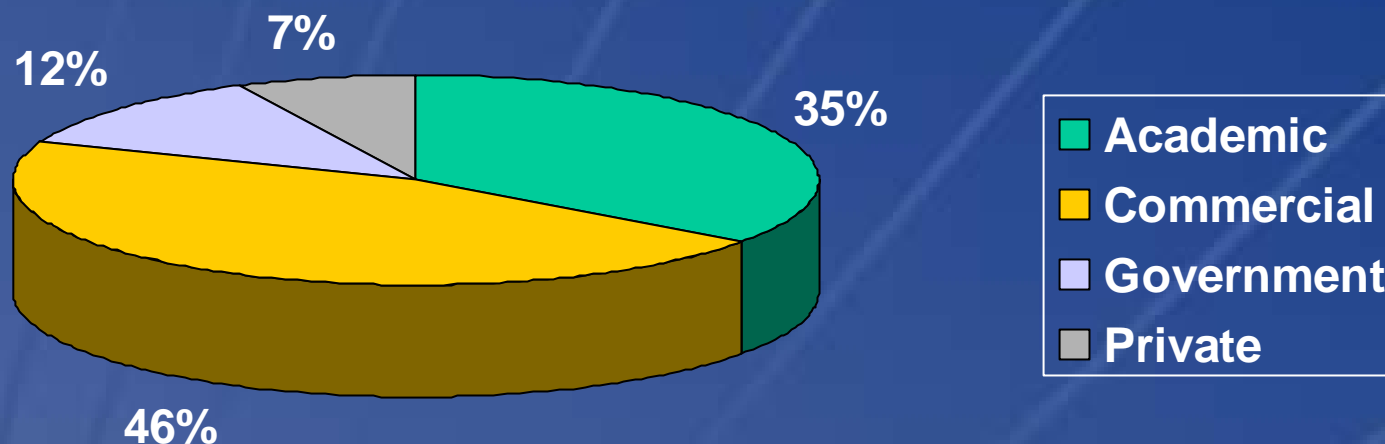
Signed: June 12, 2002

- Notice of Possession: Sec. 202 (a)
 - 30 days: Provide written guidance (*Jul. 12*)
 - 90 days: all persons shall notify DHHS of possession (*Sept. 10*)
- Interim Final Rule: Sec. 202 (b)
 - 180 days: Promulgate interim final rule (*Dec. 9*)
 - 240 days: Rule takes effect
- Interagency Coordination – overlap agents: Sec 221(c)(5)
 - 180 days MOU with USDA on overlap agents (*Dec. 9*)
 - 24 months: Joint regulation issued

PRELIMINARY NOTIFICATION OF POSSESSION RESULTS

- USDA only ~42
- HHS and/or Overlap ~1,800 (1,000)

TYPE OF ENTITY REPORTING POSSESSION



EFFECTIVE DATES

Date	Applicants Possessing Agents on or before 2/7/03	Applicants Not Possessing Agents on or before 2/7/03
Dec. 13, 2002	Publication of interim Final Rule	Publication of interim Final Rule
Feb. 7, 2003	Safety; Emergency Response; Training; Records; Notification of Theft, Loss or Release	Safety; Emergency Response; Training; Records; Notification DOJ review for entity, RO, and individuals; Transfer Section Effective
Mar. 12, 2003	Certifies that applications for DOJ review for entity and RO submitted; Transfer Section Effective	
Apr. 12, 2003	Application for DOJ review for Individuals submitted; Entity and RO DOJ review completed	
Jun. 12, 2003	Individual DOJ Review Complete; Development of Security Plan	Development of Security Plan
Sep. 12, 2003	Security Plan Implemented; Training (Security Provisions)	Security Plan Implemented; Training (Security Provisions)
Nov. 12, 2003	Registration Section Effective; Entity must be in full compliance with 42 CFR 73.0	Registration Section Effective; Entity must be in full compliance with 42 CFR 73.0

OVERVIEW OF REGULATION

42 CFR Part 73

- List of Select Agents and Toxins (HHS and Overlap)
 - Updates list of select agents and toxins
 - Toxins are regulated based on potency and quantity
 - Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms updated
 - Allows exclusion

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§ 73.4 & 73.5 HHS AND OVERLAP SELECT AGENTS AND TOXINS

- Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:
 - (1) Nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.
 - (2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed if the nucleic acids:
 - are in a vector or host chromosome and/or can be expressed in vivo or in vitro.
 - (3) Listed viruses, bacteria, fungi, and toxins that have been genetically modified.

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§ 73.4 & 73.5 HHS AND OVERLAP SELECT AGENTS AND TOXINS

- Exclusions:
 - Select agents or toxins in their naturally occurring environment, provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
 - Non-viable select agent organisms or nonfunctional toxins.
 - May exclude attenuated strains of select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety.
 - Entities with specific quantities of toxins under the control of a principal investigator.

§ 73.4 & 73.5 HHS AND OVERLAP SELECT AGENTS AND TOXINS

	<u>HHS</u>	<u>Overlap</u>
Viruses	9	4
Bacteria	3	9
Fungi	1	1
Toxins	<u>7</u>	<u>5</u>
	20	19

OVERVIEW OF REGULATION

42 CFR Part 73

- Exemptions
 - Clinical or Diagnostic Laboratories
 - Agents used only for diagnosis, verification, proficiency testing
 - Products approved under a Federal Act
 - Investigational products (must apply for exemption)
 - Public health or agricultural emergency (must apply for exemption)

OVERVIEW OF REGULATION

(continued)

- Registration of entity possessing, using, transferring select agents
- Government approval of individual to have access to select agents
 - Based on DOJ check of electronic databases
- Responsible Official
- Safety Plan
- Security Plan

OVERVIEW OF REGULATION

(continued)

- Emergency response plan
- Staff training
- Transfers
- Recordkeeping
 - Inventories
 - Access to agents
 - Access to areas where agents are stored or used
 - Transfer documents
- Notification of theft, loss, or release

MAJOR IMPACTS

- Safety
 - BMBL
 - Regulations concerning “Occupational Exposure to Hazardous Chemicals in Laboratories”
 - “NIH Guidelines for Research Involving Recombinant DNA molecules”
- Upgrading security
- Government approvals of entity, RO, and staff
- Improving recordkeeping on access
- For overlap select agents and toxins, requirement to meet both HHS and USDA regulations
- Criminal penalties and civil money penalties

COORDINATION WITH APHIS

- If an entity has overlap agents, may register with either CDC or APHIS
- If an entity has both HHS-only and USDA-only agents, must register with both agencies
- Registration package will be the same
- Agencies will coordinate approvals

Comments/Questions on New Interim Final Rule

- Submit comments in writing:
 - Mail: Centers for Disease Control and Prevention, Select Agent Program Docket Room, 1600 Clifton Road, Mailstop E-79, Atlanta, GA 30333
 - E-mail: SAPcomments@CDC.GOV
- Comments regarding the new interim final rule will be available for public viewing:
 - At the docket room (Telephone: 404-498-3242, 8:00 am - 3:00 pm EDT), Building 35, Executive Park, Atlanta
 - On our internet site: www.cdc.gov/od/sap
- Questions regarding the new interim final rule. Contact us at:
 - E-mail: lrsat@cdc.gov
 - Fax: 404-498-2265
 - Telephone: 404-498-2255